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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,983	07/21/2005	Horst G. Zerbe	AML/13131.19	7824
25545	7590	02/28/2008	EXAMINER	
GOU DREAU GAGE DUBUC 2000 MCGILL COLLEGE SUITE 2200 MONTREAL, QC H3A 3H3 CANADA			AHMED, HASAN SYED	
			ART UNIT	PAPER NUMBER
			1618	
			NOTIFICATION DATE	DELIVERY MODE
			02/28/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

[afovero@ggd.com](mailto:afovero@ggd.com)  
[Private.PAIR@ggd.com](mailto:Private.PAIR@ggd.com)

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/542,983	ZERBE ET AL.
	Examiner Hasan S. Ahmed	Art Unit 1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15 and 17-19 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) 1-15 and 17-19 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____                                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____   | 6) <input type="checkbox"/> Other: ____                           |

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim 1, drawn to a multi-layer oral dosage form comprising a matrix core allowing sustained release of a first drug, a first layer allowing sustained release of a second drug, and a second layer allowing immediate release of a second drug.

Group II, claims 1 and 2, drawn to a multi-layer oral dosage form comprising a matrix core allowing sustained release of a first drug, a first layer allowing sustained release of a first and second drug, and a second layer allowing immediate release of a second drug.

Group III, claims 1, 3, 4 and 5, drawn to a multi-layer oral dosage form comprising a matrix core comprising insoluble polymers and adjuvants, allowing sustained release of a first drug, a first layer allowing sustained release of a second drug, and a second layer allowing immediate release of a second drug.

Group IV, claims 1, 3, 4, 5, 6, and 8, drawn to a multi-layer oral dosage form comprising a matrix core comprising insoluble polymers and adjuvants, allowing sustained release of a first drug, a first layer allowing sustained release of a second drug and further comprising water-soluble and/or gel forming polymeric materials, and a second layer allowing immediate release of a second drug.

Group V, claim 1, 3, 4, 5, 7, and 9, drawn to a multi-layer oral dosage form comprising a matrix core comprising insoluble polymers and adjuvants, allowing sustained release of a first drug, a first layer allowing sustained release of a second drug, and a second layer allowing immediate release of a second drug and comprising pharmaceutically acceptable excipients.

Group VI, claims 1 and 10-13, drawn to a multi-layer oral dosage form comprising a matrix core allowing sustained release of diclofenac, a first layer allowing sustained

release of a second drug, and a second layer allowing immediate release of a second drug.

Group VII, claims 1, 10, 14, and 15, drawn to a multi-layer oral dosage form comprising a matrix core allowing sustained release of aspirin, a first layer allowing sustained release of a second drug, and a second layer allowing immediate release of a second drug. (Examiner notes that claim 15 is drafted as depending from claim 12, however, based on the content of claim 15, examiner assumed the correct dependency of claim 15 is from claim 14.)

Group VIII, claims 1, 17, 18, and 19, drawn to a multi-layer oral dosage form comprising a matrix core allowing sustained release of a first drug, a first layer allowing sustained release of an H<sub>2</sub>-receptor antagonist, and a second layer allowing immediate release of an H<sub>2</sub>-receptor antagonist.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature in all groups is a multilayered oral dosage form with an immediate release portion and a sustained release portion. Plachetka (WO 02/098352) teaches a multilayered oral dosage form with an immediate release portion and a sustained release portion (see page 3, line 29 – page 6, line 33).

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
HUMERA'N SHEIKH  
PRIMARY EXAMINER